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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,454	04/16/2004	Gregory J. LaRosa	10448-215011 / MPI98-129C	1309

26161 7590 11/15/2007
FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
CROWDER, CHUN	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
11/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,454	LAROSA ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11, 45, 47-52, 57-58, and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,45,47-52,57,58 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____. is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments, filed on October 12, 2007, are acknowledged.

Claims 1-10, 12-44, 46, 53-56, and 59 have been canceled.
Claim 60 has been added.

Claims 11, 45, 47-52, 57-58, and 60 are pending and currently under consideration as they read on the elected invention of a test kit comprising an antibody or antigen binding fragment thereof which binds to a mammalian CCR2 and inhibits binding of chemokine MCP-1 (monocyte chemotactic protein-1) without a second antibody or antigen binding fragment thereof.

2. This Office Action will be in response to applicant's arguments, filed on October 12, 2007.

The rejections of record can be found in the previous Office Action, mailed on April 13, 2007.

3. Claim 47 is objected to for being dependent upon the canceled claim 46. For examination purposes, claim 47 is read as a dependent claim of claim 11. Appropriate correction is required.

4. In light of applicant's amendment to the claims, the following New Ground of Rejection has been set forth here in.

5. This is a **New Ground of Rejection.** The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 11, 45, 47-52, 57, 58, and newly added claim 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The phrase "the amino terminal domain of a mammalian CC-chemokine receptor 2" as recited in independent claim 11 is not supported by the original disclosure or claim as filed.

Applicant's amendment, filed on October 12, 2007, directs to support to pages 5, 15, 35, and the original claims, and asserts that no new matter has been added.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitation". The specification does not provide sufficient support for an antibody that binds to "the amino terminal domain of a mammalian CC-chemokine receptor 2". The specification only discloses antibody that binds to CCR-2 or a portion of CCR-2 (see pages 5, 15, and 35, in particular); the instant claims now recite any antibody that binds to "the amino terminal domain of a mammalian CC-chemokine receptor 2", which were not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure (anti-CCR2 antibody that binds to CCR-2 or a portion of CCR-2) and possibly a single or limited species do not provide sufficient direction and guidance to the features currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitation recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 11, 45, 47, 48, 57, 58, and newly added claim 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lind et al. (US Patent 6,084,075 Reference AA on IDS filed 04/16/2004) in view of Hardiman et al. (US Patent 7,115,379) for reasons of record set forth in the previous Office Action mailed on April 13, 2007.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that some of the some of the antagonistic antibodies taught by Lin et al. were derived from using the third extracellular loop (amino acid 273-292) of CCR-2, not the claimed "the amino terminal domain of the CCR-2" as claimed; while the prior art antibodies against the amino terminal domain of the CCR-2 (amino acids 24-38) are agonistic. Therefore, applicant argues that Lind et al. do not teach an antagonistic antibody that binds to the N-terminal domain of the CCR-2. Further, applicant argues that Hardiman et al. teach a kit containing antibodies specific for a chemokine, not a chemokine receptor.

This is not found persuasive for following reasons:

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combination of references. See MPEP 2145.

It is noted that in considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01.

Furthermore, specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY); and In re Burckel 201 USPQ 67 (CCPA). In re Burckel is cited in MPEP 716.02.

In this case, in contrast to applicant's reliance on the working examples of Lind et al regarding the agonistic antibody MCPR-02, it is noted that the teachings of Lind et al. are not merely limited to theses working examples. Lind et al. identified that the N-terminal domain of the CCR2 and teach not only how to make an antibody that binds to the N-terminal domain but also how to screening for the properties of said antibody.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to make an antagonistic anti-CCR2 antibody that binds to the N-terminal domain.

Further, in contrast to applicant's assertion that the secondary reference Hardiman et al. only teach kit comprising anti-chemokine antibody, not anti-chemokine receptor antibody, it is noted that applicant has not dispute that Hardiman et al. teach that reagents such as antibody for diagnostic assays are frequently supplied to kits for optimized sensitivity of the assays. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art to collect the ingredients necessary for antibody assays into a kit for convenience and optimized standardization or to reduce error from one trial to the next. It is proper to "take account of the inferences and crative steps that a person of ordinary skill in the art would employ". *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1441, 82 USPQ2d 1385, 1396 (2007).

Furthermore, the newly added claim 60 has been included in this rejection because Lind et al. teach that the anti-CCR-2 antibody can be labeled (see Summary of the Invention on column 5, in particular).

Therefore, applicant's arguments have not been found persuasive.

11. Claim 49-52 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Lind et al. (US Patent 6,084,075 Reference AA on IDS filed 04/16/2004) and Hardiman et al. (US Patent 7,115,379) as applied to claims 11, 45, 47, 48, 57, 58, and 60 above, and further in view of Lam et al. (6,171,586) for reasons of record set forth in the previous Office Action mailed on April 13, 2007.

Applicant's arguments and the Examiner's rebuttal are essentially the same as discussed, supra.

Applicant further argues that Lam et al. discloses pharmaceutical compositing comprising antibodies in liquid forms and Lam et al. do not teach test kit comprising anti-CCR2 antibody as claimed.

This is not found persuasive for following reasons:

In contrast to applicant's assertion that Lam et al. teach liquid composition, it is noted that this argument appears to be irrelevant to the current rejection. Lam et al. is a secondary reference used to address the making and use of the human antibody, antigen-binding fragments, humanized antibody or recombinant antibody.

Given the teachings of Lind et al. regarding the anti-CCR2 antibody, Hardiman et al. providing reasons to supply antibody into a kit, and Lam et al. providing the making and the use of human antibody, antibody fragments, humanized or recombinant antibody, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed kit comprising anti-CCR2 antibody that this antagonistic and binds the N-terminal domain of CCR2 such as human antibody, antigen-binding fragments, humanized antibody and recombinant antibody for detecting the presence of a mammalian CCR2.

Therefore, applicant's arguments have not been found persuasive.

12. Conclusion: no claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Crowder, Ph.D.
Patent Examiner
November 7, 2007

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER